January 24, 2017

Re: USP Class VI – KetaSpire® KT-820 NT

Thank you for your interest in KetaSpire® KT-820 NT, manufactured by Solvay Specialty Polymers USA, L.L.C.

Enclosed please find NAMSA Laboratory's Certificate of Compliance for U.S. Pharmacopeia (USP) Biological Tests, Class VI, for the above referenced material following gamma irradiation.

Solvay Specialty Polymers is presenting this information as a courtesy and in no event shall this letter and attached information be viewed as representation of the applicability of the test results in regards to the resin of interest. Properties of materials and their lots can vary in their biological response due to a variety of factors including different types and concentration of additives as well as local manufacturing conditions.

We request each customer to conduct their own investigation and testing on the suitability of the material for the intended application. The suitability of Solvay's products in a given end-use environment is dependent upon various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the sole responsibility of the manufacturer of the final end use product to determine the suitability (including biocompatibility) of all raw materials and components, including any Solvay product, in order to ensure that the final product is biocompatible and otherwise safe for its end use, performs or functions as intended, and complies with all FDA and other regulatory requirements.

Only Solvay Specialty Polymers products designated as Solviva® family of biomaterials may be considered candidates for medical applications implanted in the human body and devices that are in contact with bodily fluids or tissues for greater than 24 hours.

If you have further questions, please feel free to contact me by telephone at 770-772-8649 or by e-mail at kendra.shoulders@solvay.com.

Sincerely,

Kendra M. Shoulders

Kendra Shoulders
Director of Global Regulatory Affairs, Healthcare

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NAMSA

CONFIDENTIAL

CERTIFICATE OF COMPLIANCE

PEOPLE > SCIENCE > SOLUTIONS

Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

TEST ARTICLE NAME
KETASPIRE KT 820 NT

TEST ARTICLE IDENTIFICATION
KT-820 NT (14880181D5)

TEST ARTICLE PHYSICAL DESCRIPTION
0.125 x 0.5 x 5" flex bars and 1 x 10 mm discs Gamma sterilized prior to submission: Two runs at target dose of 25 KGy.

TEST ARTICLE RECEIVED
August 30, 2016

SPONSOR
Kendra Shoulders
Solvay Specialty Polymers USA , L.L.C.
4500 Mcginnis Ferry Road
Alpharetta, GA 30005

USP Biological Reactivity Tests, *In Vivo*

USP Plastic Class VI

USP Systemic Toxicity Study in the Mouse

The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.

USP Intracutaneous Toxicity Study in the Rabbit

The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.

USP Muscle Implantation Study in the Rabbit

The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.

The test article was prepared at a ratio of 60 cm^2:20 mL and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.

APPROVAL Kaitlyn D. Sharp, RN, BSN
Associate Medical Research Manager

11-7-16
Date